

**Summary of the
Program Policy and Structure Committee Meeting
February 4, 1997**

The National Environmental Laboratory Accreditation Conference (NELAC) Program Policy and Structure Committee met from 10:45 a.m. to 12:05 p.m. and 1:05 to 2:30 p.m. Eastern Standard Time on Tuesday, February 4, 1997. The meeting was led by Dr. Kenneth W. Jackson, chair, of the NY State Department of Health. A list of Committee members is given in Attachment A.

INTRODUCTION

The purpose of the meeting was to review revisions to Chapter I, Program Policy and Structure, and to discuss small revisions to the Constitution and Bylaws. The following items were discussed:

- Section 1.1.4 -- Small Laboratory Operations,
- Section 1.4.2 -- Scope,
- Section 1.6.1.1 -- National Environmental Laboratory Accreditation Program,
- Sections 1.6.2/1.6.5 -- Accrediting Authorities/Assessor Bodies,
- Section 1.6.2.3.3 -- Accreditation Fees,
- Sections 1.6.4.1/1.7.3 -- Accrediting Authority Review Board,
- Section 1.7.2 -- The Environmental Laboratory Advisory Board,
- Section 1.8 -- Conduct of Conference Business,
- Section 1.9.2 -- Supplemental Requirements,
- Other issues from the floor, and
- Various articles in the constitution and bylaws.

CHAPTER 1

1.1.4 -- Small Laboratory Operations

The chair stated that small laboratories have expressed concerns that NELAC does not make accommodations for the limitations of small laboratories and asked that consideration be given to whether this section adequately deals with their concerns. The Committee agreed to add the following at the bottom of page 3: "NELAC standards have addressed ... and proficiency testing."

1.4.2 -- Scope

The chair directed attention to the last sentence of the first paragraph: “Laboratories are encouraged to use the NELAC standards for all other tests.” A question was raised about how confident one can be that a particular NELAC-accredited lab is using the NELAC standards. The Committee agreed that NELAC was not formed to regulate the client-laboratory relationship.

1.6.1.1 -- National Environmental Laboratory Accreditation Program

The chair asked the group to consider if this section clarifies the difference between NELAC and National Environmental Laboratory Accreditation Program (NELAP). NELAC is a standards-setting body; it has no authority. NELAP is the authority. A question was raised about why NELAP is evaluating and approving one principal laboratory in each State. The response was that NELAP is doing so to avoid conflicts of interest. In response to a question of why only one lab would be evaluated in each State, it was stated that the U.S. Environmental Protection Agency (USEPA) indicated it can’t evaluate every laboratory in each State because of monetary restrictions.

A panelist thought NELAP would approve an accrediting authority in each State and then the accrediting authority would approve the principal laboratory, so they suggested adding the words “accrediting authority.” The chair responded that USEPA said it is prepared to evaluate and approve one principal lab in each State. The panel member stated that Illinois EPA (IL-EPA) suggested changing the language to “primacy.” Another panel member suggested using more general language.

A participant questioned what the Committee wanted USEPA to do under (b) and the panel responded that (b) indicates that NELAC expects USEPA to pay for a national database. A participant questioned who will have access to the database. The database will be in the public domain. The Committee stated that its role was not to decide the content of the national database but only that it should be created.

1.6.2/1.6.5 -- Accrediting Authorities/Assessor Bodies

This section clarifies that there are two types of accrediting authorities, primary and secondary, and that the secondary accrediting authority agrees not to replicate any of the functions of the primary accrediting authority.

A suggestion was made to change the first partial sentence on page 10 to read “All or part of the accreditation activities” instead of “assessment activities.” The State can review the evaluation of the laboratory and give its accreditation. After some discussion, the chair responded that assessor bodies were originally called accrediting bodies. This terminology was confusing, so the NELAC Board of Directors decided to use “assessor” rather than “accrediting” because assessors don’t have any authority. The authority remains with the regulator.

The Committee agreed to change the sentence at the top of page 10 to read as follows: “If any of these assessment activities are delegated”

The Committee agreed that wording in Section 1.6.2.3.1 needs to clarify if Federal authorities are primary.

1.6.2.3.3 -- Accreditation Fees

The chair pointed out that this section has been shortened because the Committee felt that NELAC should not make any recommendation about laboratory accreditation fees, but that this section should be retained so that it is not misunderstood.

1.6.4.1/1.7.3 -- Accrediting Authority Review Board

The chair explained that the Accrediting Authority Review Board oversees NELAP to ensure that NELAP is running the program according to the standards NELAC sets. Before this meeting, the Committee received the comment that Chair of NELAC or NELAC Board should appoint, not NELAP because of conflict of interest. The panel agreed with this.

It was agreed that Section 1.6.4.1 will be merged into Section 1.7.3.

A question was raised about why the Accrediting Authority Review Board chair must be a USEPA employee, especially since it's an oversight body of USEPA. It was suggested that the chair should not be from an accrediting authority.

1.7.2 -- The Environmental Laboratory Advisory Board

The chair explained that this section should clarify the contributor's role. When it was ruled that contributors Committee was not allowed by law, USEPA established ELAB in order to give the contributors a means of providing consensus advice to NELAC.

1.8 -- Conduct of Conference Business

The chair pointed out that time specifications have been inserted, i.e, top of 20: says ... published at least 90 days prior to annual meeting, etc.

The Committee changed the time required for agenda items and resolutions to be made available before each meeting from 30 days to 35 days so that the contractor will have 5 days to get them on the bulletin board.

The Committee agreed that the notice and details of the meeting should be publicized in the local newspaper in addition to being posted on the electronic bulletin board
"http://ttnwww.rtpnc.epa.gov/html/nelac/nelac.htm#NL02".

1.9.2 -- Supplemental Requirements

This section explains that States do not have the right to change the NELAC standards. Supplemental requirements are reserved for methods or analytes that are not required under any USEPA programs that are not part of NELAC.

Wording at the end of Section 1.9.2 was changed to include "... and reviewed by NELAC and approved by NELAP."

OTHER ISSUES FROM THE FLOOR

Discussion focused on Figure 1-3 and its implications on fields of testing. While it was noted that this issue was discussed in the joint meeting with the Proficiency Testing (PT) Committee this morning, no significant changes to this figure were anticipated.

Concerns were expressed that bureaucratic roadblocks not impede timely implementation of new measurement technology. It was also noted that this structure would have to be overhauled if FIFRA/TSCA Good Laboratory Practice (GLP) analyses are included under NELAC.

A final concern was raised about the expectations of data users from the private sector. These customers are accustomed to seeing standard method usage for data generation.

Section 1.9.3 concerning general laboratory requirements was discussed at great length as it relates to issues of “health and safety and environmental compliance.” Some participants thought that “health and safety” issues were not within the purview of NELAC, while others thought they would be if such issues are included as method and standard operating procedure (SOP) requirements. The legal requirements under the Office of Safety and Health Administration (OSHA) and other regulatory demands may address these problems except for flagrant infractions that clearly jeopardize the health and safety of laboratory personnel, on-site assessors, etc. It was agreed that this issue would be revisited as a component of assessor training.

The Committee agreed that the word “other” be deleted from the last sentence in Section 1.9.3. It was also suggested that the phrase “unless specified in the method/SOP” be added to the end of the last sentence.

The Committee acknowledged having previously received detailed written comments on draft standards of Chapter 1 as a part of the position statement of the IL-EPA Division of Laboratories. It will take these comments under consideration in preparation for the Third NELAC Annual Meeting. The chair also requested that present participants (or those absent from this meeting but interested in these issues) forward other concerns or comments in writing to the Committee as soon as possible to ensure the Committee’s ability to incorporate these issues and concerns prior to the Third NELAC Annual Meeting.

AMENDMENTS TO VARIOUS ARTICLES IN THE CONSTITUTION AND BYLAWS

Amendments were proposed to four articles in the constitution and bylaws. Also proposed were two global wording changes. The amendments included the following:

1. Bylaws Article II, Section 2 -- Deletion of the following sentence: “The registration form must be completed by all potential members, whether or not attending the Annual Meeting.”
2. Bylaws Article VII, Section 1, B.2 -- Addition of an eight USEPA assistant administrator (Office of Policy Planning and Evaluation).

3. Bylaws Article VII, Section 3, C.1 -- Addition of the following sentence: “Note that any vote on amendments to the Constitution must be approved by a minimum of a two-thirds vote of the Voting Members in attendance at the Annual Meeting in both the House of Representatives and the House of Delegates.”
4. Bylaws Article VII, Section 3, C.5 -- Deletion of the following sentence: “No abstentions are recorded.”

The two global changes were as follows:

1. All references to “conference” were replaced with the term “NELAC” or “meeting,” each as appropriate.
2. The term “member” was restricted to mean “voting member.” In other cases, “member” was changed to “participant” and “membership” to “participation.”

CONCLUSION

The Committee session was adjourned at 2:45 p.m. in anticipation of a joint meeting with the Accrediting Authority Committee.

LIST OF PARTICIPANTS
Program Policy and Structure Committee Meeting
February 4, 1997

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